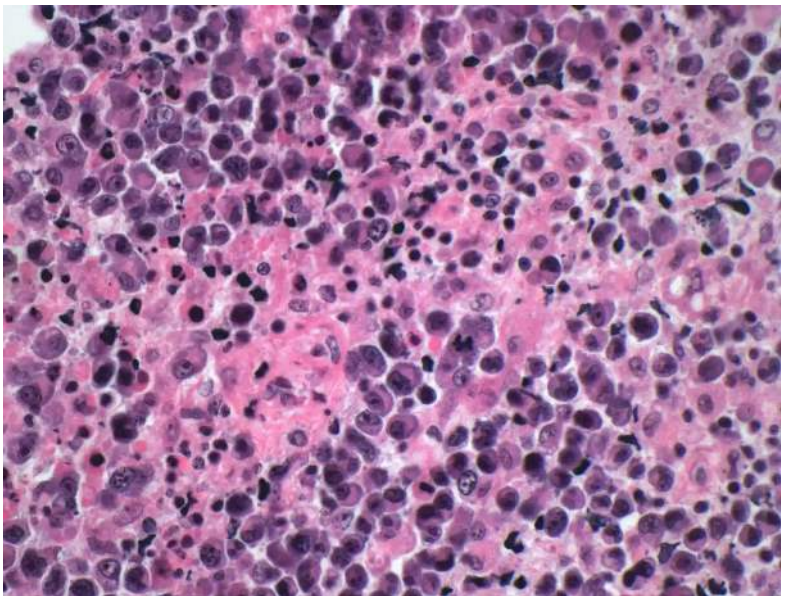
Onco-this-Week

February 10, 2019(https://sciwri.club/archives/date/2019/02/10)



DRUG APPROVALS

FDA approves Ibrutinib + Obinutuzumab in 1L CLL patients based on Ph III iLLUMINATE trial results (https://www.janssen.com/us-fda-approves-imbruvica-ibrutinib-plus-obinutuzumab-first-non-chemotherapy-combination-regimen)

"This label update builds upon the established efficacy and safety of IMBRUVICA in the frontline treatment of patients with CLL/SLL, as a monotherapy or in combination with other treatments," said Craig Tendler, M.D., Vice President, Clinical Development and Global Medical Affairs, Janssen Research & Development, LLC. "This milestone represents our continued commitment to develop IMBRUVICA-based, non-chemotherapy regimens to address the clinical needs of patients living with CLL/SLL."

> BREAKING NEWS: The @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) has approved the use of ibrutinib (Imbruvica®, AbbVie) in combination with obinutuzumab (Gazyva®) for adult patients with previously untreated chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL). Read more: https://t.co/KsMp5pwqk6 (https://t.co/KsMp5pwqk6) pic.twitter.com/txNR17cUIW (https://t.co/txNR17cUIW)
>
> — The Leukemia & Lymphoma Society – Policy Advocacy (@LLSAdvocacy) January 28, 2019 (https://twitter.com/LLSAdvocacy/status/1089983180822724614?ref_src=twsrc%5Etfw)

FDA expands Pemetrexed label with Pembrolizumab and platinum chemotherapy in 1L non-sq mNSCLC patients (https://investor.lilly.com/news-releases/news-release-details/fda-expands-lillys-alimtar-pemetrexed-label-combination)

"KEYNOTE-189 demonstrated an exceptional effect of the ALIMTA-pembrolizumab-platinum chemotherapy combination in the first-line setting, offering significantly improved survival in patients with metastatic nonsquamous non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations," said Anne White, president, Lilly Oncology. "This new indication reinforces Lilly's continued commitment to providing practice-changing treatment options that can make a meaningful difference for people living with lung cancer."

> Alimta (pemetrexed) and Keytruda (pembrolizumab) with carboplatin combo recieves FDA approval in #lungcancer (https://twitter.com/hashtag/lungcancer?src=hash&ref_src=twsrc%5Etfw) https://t.co/F56La5T6E7 (https://t.co/F56La5T6E7)
>
> — PRICENTRIC (@PricentricALSCG) February 1, 2019 (https://twitter.com/PricentricALSCG/status/1091301567259500545?ref_src=twsrc%5Etfw)

REGULATORY NEWS

IND cleared for iPSC-derived NK cell therapy, FT516, for treatment of hematologic malignancies (https://ir.fatetherapeutics.com/news-releases/news-release-details/fate-therapeutics-announces-fda-clearance-ind-application-worlds)

> NK cells paving the way. First IND clearance for a gene-edited iPSC-derived cell therapy product... https://t.co/O1spC5Zblo (https://t.co/O1spC5Zblo)
>
> — MalmbergLab (@MalmbergLab) February 7, 2019 (https://twitter.com/MalmbergLab/status/1093375999851425792?ref_src=twsrc%5Etfw)

"This allowance by the FDA of our FT516 IND application is a watershed event in the clinical development of engineered cell therapies. Our industry-leading iPSC product platform enables the manufacture of engineered cell products that can be extensively characterized, cryopreserved and delivered 'on demand' to reach more patients," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "FT516 is a first-of-kind cell product in that it originates from a single genetically engineered pluripotent stem cell, which serves as a clonal master cell line that can be repeatedly used to mass-produce large quantities of homogeneous cell product in a cost-effective manner. This innovative approach uniquely supports a new treatment paradigm with engineered cell therapies, where multiple doses of cell product are readily available for administration with the goal of driving deeper and more durable responses. We look forward to treating patients with multiple doses of FT516, including in combination with FDA-approved monoclonal antibody therapy, across multiple treatment cycles in this first clinical study."

sBLA submitted for adjuvant trastuzumab emtansine in early stage HER2+ breast cancer patients based on Ph III KATHERINE trial results (http://hugin.info/174806/R/2233433/878589.pdf)

"Kadcyla was granted Breakthrough Therapy Designation and is also the first Roche medicine to be reviewed under the FDA's Real-Time Oncology Review pilot programme; both FDA initiatives aim to expedite reviews and bring medicines to patients sooner" said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "We are working closely with the FDA to bring Kadcyla to people with HER2-positive early breast cancer who have residual disease after neoadjuvant therapy as early as possible."

> The drug trastuzumab emtansine (Kadcyla®) improves survival for some patients with metastatic breast cancer: https://t.co/do433GC4iH (https://t.co/do433GC4iH) #bcsm (https://twitter.com/hashtag/bcsm?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/VnMosxfDQn (https://t.co/VnMosxfDQn)
>
> — National Cancer Institute (@theNCI) August 26, 2017 (https://twitter.com/theNCI/status/901244065588666369?ref_src=twsrc%5Etfw)

Revised OS HR value prompts FDA to recommend postponing NDA for VEGF TKI Tivozanib in R/R RCC patients (https://www.aveooncology.com/wp-content/uploads/2019/01/AVEO-Regulatory-Update-20190131.pdf)

"We are hopeful that the positive PFS outcome will translate into an improved hazard ratio when we evaluate a more mature interim OS outcome in the fourth quarter of 2019," said Michael Bailey, president and chief executive officer of AVEO. "We look forward to continuing to work with the FDA to determine tivozanib's benefit-risk profile as a single agent in RCC patients."

> Based on a recommendation from the FDA, Aveo Oncology has decided not to submit a new drug application for tivozanib...https://t.co/H5AbJQCiN3 (https://t.co/H5AbJQCiN3)#KidneyCancer (https://twitter.com/hashtag/KidneyCancer?src=hash&ref_src=twsrc%5Etfw) #rccsm (https://twitter.com/hashtag/rccsm?src=hash&ref_src=twsrc%5Etfw) #kcsm (https://twitter.com/hashtag/kcsm?src=hash&ref_src=twsrc%5Etfw)
>
> — Targeted Oncology (@TargetedOnc) February 5, 2019 (https://twitter.com/TargetedOnc/status/1092679304708804608?ref_src=twsrc%5Etfw)

CTA approval granted to FGFR4 inhibitor BLU-554 (CS3008) in China to start Ph I trial in TKI-naive HCC patients (https://www.prnewswire.com/news-releases/cstone-receives-cta-approval-in-china-to-start-phase-i-trial-for-fgfr4-inhibitor-blu-554-cs3008-300785598.html)

> CStone receives CTA approval in China to start Phase I trial for FGFR4 inhibitor BLU-554 (CS3008) $BPMC (https://twitter.com/search?q=%24BPMC&src=ctag&ref_src=twsrc%5Etfw) https://t.co/nO28mDoGBt (https://t.co/nO28mDoGBt)
>
> — Odi Bruckman (@odibro) January 29, 2019 (https://twitter.com/odibro/status/1090181950193745920?ref_src=twsrc%5Etfw)

Dr. Frank Jiang, CEO and chairman of CStone, commented: "Compared with current treatments, BLU-554 has produced encouraging data in terms of tolerability and disease control rates. We also plan to conduct a Phase I trial of BLU-554 in combination with CS1001 for the treatment of advanced HCC patients in China in the second half of 2019. Our hope is to make more effective treatment options available to HCC sufferers."

NDA accepted by NMPA for bevacizumab biosimilar IBI-305 in advanced non-squamous NSCLC patients (http://innoventbio.com/en/#/news/128)

> Innovent Biologics Reports Acceptance of BLA for IBI-305 (bevacizumab, biosimilar) from NMPA (CFDA) to Treat NSCLC https://t.co/nvQTQEvJUp (https://t.co/nvQTQEvJUp) pic.twitter.com/k2wYtc3h8g (https://t.co/k2wYtc3h8g)
>
> — PharmaShots (@Pharmashot) January 29, 2019 (https://twitter.com/Pharmashot/status/1090194562897903616?ref_src=twsrc%5Etfw)

"We are delighted that IBI-305 has become our third NDA successfully accepted by the NMPA. At the present time we have thirteen products in clinical development stage and four products in Phase 3 clinical trials. Tyvyt®, our first commercial product, was recently approved by NMPA and our team will continue to deliver high quality biopharmaceutical drugs from our rich pipeline to benefit more ordinary people in China and globally," said Michael Yu, Founder, Chief Executive Officer and Chairman of Innovent.

IND approval granted to anti-CD47 mAb, TJC4, to initiate Ph I/Ib trials in solid tumors and lymphoma as monotherapy and combination therapies (http://www.i-mabbiopharma.com/en/article-294.aspx)

> I-Mab Biopharma, a China-based clinical stage biopharmaceutical company announced on Jan. 25, 2019 that it received approval of IND application from US FDA for TJC4, a Potential Global Best-in-Class Anti-CD47 Monoclonal Antibody. https://t.co/CUAf3YruMb (https://t.co/CUAf3YruMb)
>
> — Chinese Antibody Society (@ChineseAntibody) January 29, 2019 (https://twitter.com/ChineseAntibody/status/1090167307597275136?ref_src=twsrc%5Etfw)

"This approval lays the foundation for I-Mab's global clinical development of our innovative and globally competitive proprietary candidates in the field of immuno-oncology." Expressed by Dr. Joan Shen, Head of R&D at I-Mab, "We believe that the unique epitope and potential better safety profile clearly differentiate TJC4 from other agents targeting CD47/SIRPα pathway in development, which may translate into improved clinical benefits to patients with various types of malignancies."

CARsgen Therapeutics receives IND clearance for GPC3-CAR-T cells in solid tumors from the NMPA (https://www.prnewswire.com/news-releases/carsgen-therapeutics-receives-ind-clearance-for-gpc3-car-t-cells-from-the-nmpa-300785789.html)

> China gets its first IND clearance for #CART (https://twitter.com/hashtag/CART?src=hash&ref_src=twsrc%5Etfw) cell therapy against solid tumors. #CARsgenTherapeutics (https://twitter.com/hashtag/CARsgenTherapeutics?src=hash&ref_src=twsrc%5Etfw) is developing humanized GPC3-CAR-T cell for GPC3-positive #SolidTumors (https://twitter.com/hashtag/SolidTumors?src=hash&ref_src=twsrc%5Etfw).https://t.co/aOFbT4t3QX (https://t.co/aOFbT4t3QX)
>
> — DRG China In Depth (@drg_in) February 6, 2019 (https://twitter.com/drg_in/status/1093058248746225664?ref_src=twsrc%5Etfw)

"The IND clearance of GPC3-CAR-T cells by China's NMPA is of great significance to CARsgen," said Dr. Zonghai Li, founder, CEO and CSO of CARsgen. "Solid tumors, particularly hepatocellular carcinoma, represent major health challenges due to increasing incidence and limited available therapeutic solutions. In China, the estimated annual incidence of HCC has already reached 467,000[1]. While in the U.S., HCC is also a leading cause of death with 37,948 new cases every year [2]. To cope with the situation, we plan to submit IND Application for GPC3-CAR-T cells to FDA by the end of 2019. Our goal is to continue the development of novel, safe and effective immunotherapies. This is our long-standing commitment to cancer patients worldwide."

FDA clearance to IND for ALLO-501, a CD19 allogeneic CAR T (AlloCAR T) therapy, to initiate Ph I ALPHA trial in R/R NHL patients (https://ir.allogene.com/news-releases/news-release-details/allogene-therapeutics-collaboration-servier-announces-fda)

> Servier and @AllogeneTx (https://twitter.com/AllogeneTx?ref_src=twsrc%5Etfw)-a pioneering biotech company in the development of allogeneic CAR-T cancer therapies-are announcing the @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) approval for the early clinical development of ALLO-501:an allogeneic CAR-T anti-CD19 therapy for the treatment of relapsed non-Hodgkin lymphoma pic.twitter.com/scYrMuDv4j (https://t.co/scYrMuDv4j)
>
> — Servier (@servier) January 28, 2019 (https://twitter.com/servier/status/1089897274753380354?ref_src=twsrc%5Etfw)

"I am very pleased with the Allogene team's ability to accelerate the ALLO-501 program by securing the FDA's clearance of our IND," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "This significant milestone for the company, as well as the planned initiation of the ALPHA trial, brings us one step closer to making CAR T therapy 'on demand' and more broadly accessible to patients when they are at a critical stage in their disease."

SPECIAL STATUSES

FDA orphan drug designation granted to STAT3 inhibitor, WP1066, in GBM (https://ir.moleculin.com/press-releases/detail/113/moleculin-announces-the-fda-has-granted-orphan-drug)

> FDA grants Orphan Drug Designation to $MBRX (https://twitter.com/search?q=%24MBRX&src=ctag&ref_src=twsrc%5Etfw) 's WP1066 for the treatment of glioblastoma, the most aggressive form of brain tumor https://t.co/kVDS682393 (https://t.co/kVDS682393)
>
> — Hottest Stocks Now (@HottestStockNow) February 5, 2019 (https://twitter.com/HottestStockNow/status/1092806560512991238?ref_src=twsrc%5Etfw)

"We continue to be encouraged by the progress of the physician-led clinical trial of WP1066," commented Walter Klemp, Moleculin's Chairman and CEO, "and, now having the FDA grant Orphan Drug status for WP1066 positions us well for potential marketing of this drug. We believe that WP1066 represents a new class of drugs which we call 'Immune/Transduction Modulators' because it has demonstrated the ability in preclinical testing in animals to both stimulate a natural immune response to tumors and directly attack tumor cells by inhibiting multiple key oncogenic transcription factors, including STAT3, HIF1-α and c-Myc."

FDA priority review granted to CSF1R Inhibitor Pexidartinib for tenosynovial giant cell tumor (TGCT) patients based on Ph III ENLIVEN trial results; PDUFA: Aug 3, 2019 (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006968.html)

> The FDA has granted a priority review designation to a NDA for the investigational, small molecule, CSF1R receptor inhibitor pexidartinib for the treatment of adult patients with symptomatic TGCT #sarcsm (https://twitter.com/hashtag/sarcsm?src=hash&ref_src=twsrc%5Etfw) https://t.co/1bypNsBtqR (https://t.co/1bypNsBtqR)
>
> — OncLive.com (@OncLive) February 6, 2019 (https://twitter.com/OncLive/status/1093041672097800194?ref_src=twsrc%5Etfw)

"We are pleased to announce that the FDA has accepted our application for pexidartinib with Priority Review designation, potentially bringing a treatment option to patients for whom there is no approved therapy," said Dale Shuster, Ph.D., Executive Director, Global Oncology R&D, Daiichi Sankyo. "Current treatment options for TGCT are largely limited to surgery, but for some patients the disease is debilitating and not amenable to improvement with surgery. We are committed to working with the FDA to potentially bring pexidartinib to carefully-selected patients as soon as possible."

FDA grants Orphan Drug Designation to BL-8040 for the treatment of pancreatic cancer (http://www.biolinerx.com/default.asp?pageid=16&itemid=647)

> Short peptide drug as antagonist for CXCR4 in pancreatic cancer. BioLineRX's BL-8040 Receives FDA's Orphan Drug Designation (ODD) for Pancreatic Cancer | PharmaShots https://t.co/YYSm5kqgVx (https://t.co/YYSm5kqgVx)
>
> — Kai Song (@song_kk) February 7, 2019 (https://twitter.com/song_kk/status/1093498705901166592?ref_src=twsrc%5Etfw)

"Orphan Drug Designation in pancreatic cancer is a very important milestone in the development plan of BL-8040, and joins previously approved orphan designations by the FDA for BL-8040 in AML and stem-cell mobilization," stated Philip Serlin, Chief Executive Officer of BioLineRx. "Despite advances in the treatment of various cancers with immune checkpoint inhibitors, pancreatic cancer is refractory to these treatment options, and remains an area of significant unmet medical need. We have previously reported encouraging clinical data supporting the potential of BL-8040 as part of an immunotherapy combination treatment in pancreatic cancer, and we look forward to top-line results from our ongoing pancreatic clinical studies later this year."

FDA orphan designation granted to anti-CD32B mAb BI-1206 in MCL (http://www.bioinvent.com/media/press-releases/releases?id=9C91D1D0A78CD6B0)

"This orphan designation for BI-1206 is very good news for BioInvent, and most importantly for patients suffering from this very serious condition. There is a significant unmet medical need, as there are presently few treatment options for patients suffering from mantle cell lymphoma. We are looking forward to generating data from our Phase I/IIa trial to support the use of BI-1206 in combination with rituximab in this indication," says Martin Welschof, CEO of BioInvent.

CHMP recommends EU approval of Atezolizumab + bevacizumab and chemotherapy in 1L NSCLC (https://www.roche.com/media/releases/med-cor-2019-02-01b.htm)

> The CHMP adopted a positive opinion recommending the approval of #atezolizumab (https://twitter.com/hashtag/atezolizumab?src=hash&ref_src=twsrc%5Etfw) + #bevacizumab (https://twitter.com/hashtag/bevacizumab?src=hash&ref_src=twsrc%5Etfw) + chemotherapy as frontline treatment for metastatic non-squamous #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw). This recommendation is based on results from the Phase III #IMpower150 (https://twitter.com/hashtag/IMpower150?src=hash&ref_src=twsrc%5Etfw) study#checkpointcombinations (https://twitter.com/hashtag/checkpointcombinations?src=hash&ref_src=twsrc%5Etfw) #lungcancer (https://twitter.com/hashtag/lungcancer?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/rbHPFTVejI (https://t.co/rbHPFTVejI)
>
> — Beacon Intelligence (@BeaconIntel) February 5, 2019 (https://twitter.com/BeaconIntel/status/1092815111113396224?ref_src=twsrc%5Etfw)

"We are pleased to receive a positive opinion from the CHMP for this Tecentriq-based combination, which represents a significant step towards bringing a new treatment option to people across Europe with advanced, non-squamous non-small cell lung cancer," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global

Product Development. “The IMpower150 study, on which this opinion is based, demonstrated an overall survival benefit, including those in key populations such as people with EGFR- or ALK-positive mutations or liver metastases.”

Positive CHMP Opinion granted to Dacomitinib in 1L EGFR+ NSCLC patients (https://www.pfizer.com/news/press-release/press-release-detail/pfizer_receives_positive_chmp_opinion_for_vizimpro_dacomitinib_for_the_first_line_treatment_of_adult_patients_with_locally_advanced_or_metastatic_non_

> Dacomitinib for EGRF+ lung cancer gets EU OK. https://t.co/ghqotTjICA (https://t.co/ghqotTjICA) pic.twitter.com/FlaLjjvuMh (https://t.co/FlaLjjvuMh)
>
> — Medscape Oncology (@MedscapeOnc) February 5, 2019 (https://twitter.com/MedscapeOnc/status/1092917285667377154?ref_src=twsrc%5Etfw)

“Patients with EGFR-mutated non-small cell lung cancer, a disease that is associated with low overall survival rates, are in need of more treatment options. This positive CHMP opinion is an important step toward bringing this treatment to patients in Europe as a potential new first-line treatment option,” said Chris Boshoff, M.D., Ph.D., Chief Development Officer, Oncology, Pfizer Global Product Development. “Vizimpro’s development is a direct result of Pfizer’s focus on precision drug development to create tailored options that improve patient outcomes.”

Fast Track designation granted to anti-KIR3DL2 cytotoxicity-inducing antibody IPH4102 for the treatment of adult patients with R/R Sézary syndrome (SS) (https://www.innate-pharma.com/en/news-events/press-releases/innate-pharma-receives-fda-fast-track-designation-iph4102-relapsed-or-refractory-sezary-syndrome)

> Check out our latest press release : “@InnatePharma (https://twitter.com/InnatePharma?ref_src=twsrc%5Etfw) receives FDA fast track designation for IPH4102 in relapsed or refractory Sézary syndrome” https://t.co/2s0PJqxWts (https://t.co/2s0PJqxWts) pic.twitter.com/XjXpgIV4KX (https://t.co/XjXpgIV4KX)
>
> — Innate Pharma (@InnatePharma) January 29, 2019 (https://twitter.com/InnatePharma/status/1090127498115989504?ref_src=twsrc%5Etfw)

“We are pleased that the FDA has granted Fast Track designation to IPH4102 as there remains a high need for treatment options with strong efficacy and adequate safety profile to allow for treatment of Sézary syndrome, the most aggressive form of cutaneous T-cell lymphoma (CTCL),” said Pierre Dodion, Chief Medical Officer of Innate Pharma. “IPH4102 is a key element of our strategy to build a commercial franchise of treatments focused on rare cancers in the field of hemato-oncology. We intend to initiate a global multi-cohort Phase II study (TELLOMAK) in the first half of 2019 to confirm the clinical activity of IPH4102 in Sézary syndrome and evaluate the potential in other subtypes of T-cell lymphomas, including Mycosis fungoides (MF) and peripheral T-cell lymphoma (PTCL). We look forward to working with the FDA to advance this promising program through clinical development.”

Zai Lab’s ZL-2306 (niraparib) granted Priority review in China as maintenance therapy in ovarian cancer patients (https://zailab.gcs-web.com/news-releases/news-release-details/priority-review-granted-zai-labs-nda-application-zejula)

“The granting of priority review for ZEJULA by the NMPA highlights both urgency of the medical need and the potential importance of ZEJULA as an innovative therapeutic option for Chinese women suffering from this difficult to treat cancer,” said Dr. Samantha Du, Chairman and Chief Executive officer of Zai Lab. “We will continue to work closely with the agency to bring this novel treatment to patients as soon as possible.”

TRIAL RESULTS

Encouraging preliminary results observed with Tisotumab vedotin in Ph I/II InnovaTV 201 trial of heavily pre-treated advanced or metastatic solid tumors patients (https://www.icr.ac.uk/news-archive/new-trojan-horse-cancer-treatment-shows-early-promise-in-multiple-tumour-types)

> ‘Trojan horse’ drug attacks tumours from the inside https://t.co/RO2QcBVsln (https://t.co/RO2QcBVsln)
>
> A ‘Trojan horse’ drug that attacks tumour cells from within may offer hope to cancer patients with few options left.
>
> A study found the treatment – tisotumab vedotin (TV) – pr... https://t.co/RO2QcBVsln (https://t.co/RO2QcBVsln) pic.twitter.com/fhyvikJ030 (https://t.co/fhyvikJ030)
>
> — healthmedicinet (@healthmedicinet) February 9, 2019 (https://twitter.com/healthmedicinet/status/1094199508764971008?ref_src=twsrc%5Etfw)

Professor Johann de Bono, Regius Professor of Cancer Research at The Institute of Cancer Research, London, and Consultant Medical Oncologist at The Royal Marsden NHS Foundation Trust, said:

“What is so exciting about this treatment is that its mechanism of action is completely novel – it acts like a Trojan horse to sneak into cancer cells and kill them from the inside. Our early study shows that it has the potential to treat a large number of different types of cancer, and particularly some of those with very poor survival rates.

“TV has manageable side effects, and we saw some good responses in the patients in our trial, all of whom had late-stage cancer that had been heavily pre-treated with other drugs and who had run out of other options.

“We have already begun additional trials of this new drug in different tumour types and as a second-line treatment for cervical cancer, where response rates were particularly high. We are also developing a test to pick out the patients most likely to respond.”

Strong interim clinical data announced from Ph IIb trial of Type II IL4R-targeting fusion protein, MDNA55, in R/R GBM patients (https://ir.medicenna.com/2019-02-07-Medicenna-Presents-Promising-Clinical-Data-from-Phase-2b-Recurrent-Glioblastoma-Trial-of-MDNA55)

> Dr John Sampson, Duke University School of Medicine, describes the role of IL4R expression on survival outcomes and the therapeutic benefit from MDNA55 treatment #io360nyc (https://twitter.com/hashtag/io360nyc?src=hash&ref_src=twsrc%5Etfw) @DukeU (https://twitter.com/DukeU?ref_src=twsrc%5Etfw) pic.twitter.com/ntFwxjupog (https://t.co/ntFwxjupog)
>
> — The Conference Forum (@ConferenceForum) February 7, 2019 (https://twitter.com/ConferenceForum/status/1093620409965137920?ref_src=twsrc%5Etfw)

"These preliminary data showing longer median survival in MDNA55-treated subjects with positive IL4R expression are highly encouraging and could help determine which subjects will receive optimal therapeutic benefit from MDNA55 treatment," states Dr. Martin Bexon, Head of Clinical Development at Medicenna. "As the second half of our trial continues to enroll at higher doses of MDNA55, we expect to see more data supporting IL4R as an important biomarker and immunotherapeutic target for rGBM and to improve the benefit-risk profile for subjects treated with MDNA55." The safety and tolerability of MDNA55 has generally remained within the profile established in previous studies.

Primary endpoint of PFS improvement met in pivotal Ph III SOPHIA trial of Margetuximab + chemo in HER2+ breast cancer (http://ir.macrogenics.com/news-releases/news-release-details/macrogenics-announces-positive-results-pivotal-phase-3-sophia)

> MacroGenics' margetuximab beats Herceptin in phase 3. Will the improvement in PFS over Herceptin lead to an approval in the second half of the year? #bcsm (https://twitter.com/hashtag/bcsm?src=hash&ref_src=twsrc%5Etfw) https://t.co/2iM3BtFUJr (https://t.co/2iM3BtFUJr) $MGNX (https://twitter.com/search?q=%24MGNX&src=ctag&ref_src=twsrc%5Etfw) pic.twitter.com/Xiaw8iJaMi (https://t.co/Xiaw8iJaMi)
>
> — Bionest Partners (@BionestPartners) February 8, 2019 (https://twitter.com/BionestPartners/status/1093874596691017728?ref_src=twsrc%5Etfw)

"There are currently no approved agents for the treatment of patients with metastatic HER2+ breast cancer who have previously received trastuzumab, pertuzumab and ado-trastuzumab emtansine. If margetuximab is approved, based on SOPHIA data, I believe that this agent could become a valuable treatment option for these patients," said Hope S. Rugo, M.D., Director, Breast Oncology and Clinical Trials Education, University of California San Francisco Comprehensive Cancer Center.

Activation of Th17 lymphocytes show statistically significant association with long-term survival as per serum biomarker analyses on patient samples from rPh II trial of AVOVA-1 therapy (https://www.prnewswire.com/news-releases/predictive-markers-of-survival-identified-for-next-generation-cancer-stem-cell-vaccine-300790227.html)

"Our data suggest that Th17 cells in untreated cancer patients have an antigen repertoire that is incomplete or below a sufficient signal-strength threshold to be effective," said Dr. Gabriel Nistor, AIVITA's Chief Science Officer. "It is clear that AIVITA's cancer stem cell vaccine elevates an appropriate antigenic signal in all immune responding cells, and particularly induces a cytotoxic transformation of the Th17 subpopulation."

Primary endpoint of PFS improvement met in Ph III ICARIA-MM trial of anti-CD38 mAb Isatuximab (+pomalidomide and low dose dexamethasone) in RRMM patients (http://hugin.info/152918/R/2233412/878603.pdf)

> Sanofi reports positive data for myeloma drug isatuximab, but competitive uphill battle lies ahead https://t.co/l6KYi23s5Q (https://t.co/l6KYi23s5Q) pic.twitter.com/dKru282mKK (https://t.co/dKru282mKK)
>
> — Dr. Osama AbouElKhir (@DrOsamaAhmed) February 9, 2019 (https://twitter.com/DrOsamaAhmed/status/1094317147344392192?ref_src=twsrc%5Etfw)

"We are excited by these results, which represent significant progress in our ambition to extend the lives of multiple myeloma patients," said John Reed, Head of Research and Development at Sanofi. "We look forward to engaging with regulatory authorities with the goal of bringing this potential new treatment to patients as quickly as possible."

Data from Ph I trial of Ublituximab, Umbralisib, and Ibrutinib in R/R B-cell malignancies published (http://ir.tgtherapeutics.com/news-releases/news-release-details/tg-therapeutics-inc-announces-publication-clinical-data-phase-i)

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated "We want to thank Dr. Loretta Nastoupil and the MD Anderson Cancer Center, as well as each of the participating trial sites and most importantly the patients who participated in this study. Umbralisib has demonstrated unique combinability with other targeted agents, and the data included in this publication further support our goal of developing a proprietary triple combination of ublituximab, umbralisib and our own BTK inhibitor, TG-1701, for which we target commencing clinical trials later this year."

Primary endpoint met; 24% ORR observed in ongoing KEYNOTE-695 trial of TAVO +Pembrolizumab in metastatic/recurrent melanoma patients (https://ir.oncosec.com/press-releases/detail/1979/oncosec-provides-keynote-695-clinical-update-and-outlines)

> After PISCES/KEYNOTE-695 the 2nd Ph2 trial starts combo of TAVO & #KEYTRUDA (https://twitter.com/hashtag/KEYTRUDA?src=hash&ref_src=twsrc%5Etfw)$ONCS (https://twitter.com/search?q=%24ONCS&src=ctag&ref_src=twsrc%5Etfw) Initiates KEYNOTE-890, a Ph2 Clinical Trial of TAVO in Combination with Merck's #KEYTRUDA (https://twitter.com/hashtag/KEYTRUDA?src=hash&ref_src=twsrc%5Etfw) (pembrolizumab) for the Treatment of Late-Stage Triple Negative Breast Cancer #TNBC (https://twitter.com/hashtag/TNBC?src=hash&ref_src=twsrc%5Etfw)https://t.co/IUlYhsz9Ss (https://t.co/IUlYhsz9Ss)
>
> — Joe (@GantosJ) October 15, 2018 (https://twitter.com/GantosJ/status/1051800379606913024?ref_src=twsrc%5Etfw)

“2018 was a busy and productive year for OncoSec, and as we enter 2019, we are well-positioned to continue advancing our lead program, TAVO™, towards registration in multiple tumor settings in the United States beginning as early as 2020,” said Daniel O’Connor, OncoSec’s Chief Executive Officer. “Our focus in 2019 will be moving TAVO™ towards registration in our current indication of PD-1 refractory, late-stage melanoma, progressing our recently announced registration-enabled clinical study in cervical cancer, expanding our ability to target tumors affecting internal organs, advancing a new, second pipeline candidate for which we expect to file an IND in 2019, and completing KEYNOTE-890, our combination study with TAVO + KEYTRUDA® in TNBC. We believe that executing on this plan will extend the long-term valuation of our company and, most importantly, bring meaningful new treatments to patients and clinicians who very much need them.”

Apalutamide Ph III TITAN study unblinded as dual primary endpoints achieved in mCRPC patients (https://www.jnj.com/janssen-announces-erleada-apalutamide-phase-3-titan-study-unblinded-as-dual-primary-endpoints-achieved-in-clinical-program-evaluating-treatment-of-patients-with-metastatic-castration-sensitive-prostate-cancer)

> New Drug: Apalutamide for prostate cancer. https://t.co/fc4PWnKGLW (https://t.co/fc4PWnKGLW) pic.twitter.com/6fs4ezFPx0 (https://t.co/6fs4ezFPx0)
>
> — AustralianPrescriber (@AustPrescriber) February 9, 2019 (https://twitter.com/AustPrescriber/status/1094158993470164992?ref_src=twsrc%5Etfw)

“The TITAN study was designed to evaluate the efficacy and safety of ERLEADA in combination with androgen deprivation therapy in patients with newly-diagnosed metastatic castration-sensitive prostate cancer, regardless of the extent of their disease,” said Margaret Yu, M.D., Vice President, Oncology Clinical Development, Janssen Research & Development, LLC. “We look to continue to build upon our understanding of ERLEADA for patients with metastatic prostate cancer as there remains a significant unmet need for additional treatment options.”

TRIAL STATUSES

Novel Ph I/II combination trial of Actimab-A and Venetoclax initiated in R/R AML patients (https://ir.actiniumpharma.com/press-releases/detail/314/actinium-initiates-novel-phase-12-combination-trial-of)

> $ATNM (https://twitter.com/search?q=%24ATNM&src=ctag&ref_src=twsrc%5Etfw) Actinium Initiates Novel Phase 1/2 Combination Trial of Actimab-A and Venetoclax https://t.co/9Za9cwlNMn (https://t.co/9Za9cwlNMn) via @YahooFinance (https://twitter.com/YahooFinance?ref_src=twsrc%5Etfw)
>
> — PJ (@pjf949) February 5, 2019 (https://twitter.com/pjf949/status/1092787769410113536?ref_src=twsrc%5Etfw)

Dr. Dale Ludwig, Actinium’s Chief Scientific Officer said, “The ability to deplete MCL-1, a known resistance mechanism to venetoclax, by selectively targeting AML cells that express CD33 with Actimab-A and hitting them with potent alpha radiation from Actinium-225 is very compelling. I am excited to see this study enter the clinic as I believe Actimab-A’s targeted radiation will prove to be synergistic with venetoclax as we have shown in our preclinical work. With our powerful Antibody Warhead Enabling technology platform we are excited to deploy targeted radiation as a weapon against cancer cells by exploiting their susceptibility to radiation and leveraging potential synergies with other therapeutic modalities.”

Patient enrolment completed in rPh II ENTRATA trial of glutaminase inhibitor Telaglenastat (CB-839) and Everolimus in ccRCC patients (http://ir.calithera.com/news-releases/news-release-details/calithera-biosciences-completes-patient-enrollment-randomized?field_nir_news_date_value%5bmin%5d=)

> $CALA (https://twitter.com/search?q=%24CALA&src=ctag&ref_src=twsrc%5Etfw) Completes Patient Enrollment in Randomized Phase 2 ENTRATA Trial of Telaglenastat CB839 and Everolimus in RCC. Top line Data in 2H 2019 https://t.co/mPw9QokPPI (https://t.co/mPw9QokPPI).comnewscalitherabiosciencescompletespatientenrollment120500685.htmlÂ: $CALA... https://t.co/H2J5wPG33C (https://t.co/H2J5wPG33C) #patient (https://twitter.com/hashtag/patient?src=hash&ref_src=twsrc%5Etfw)
>
> — Patient Monitoring (@PatientMonitor) February 4, 2019 (https://twitter.com/PatientMonitor/status/1092446321879920641?ref_src=twsrc%5Etfw)

“The ENTRATA trial is the first randomized trial evaluating the glutaminase inhibitor telaglenastat. There is ample evidence demonstrating the potential of glutaminase inhibition to block growth and survival of cancer cells,” said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. “We are pleased that patient enrollment is now complete and look forward to learning more from ENTRATA about how this promising mechanism could help heavily pre-treated patients with advanced renal cancer.”

Early results from Ph IIa CEND1-001 trial of tumor-penetrating peptide CEND-1 in pancreatic cancer patients show high response rates, favorable safety profile, and no DLTs; CEND-1 gets FDA orphan drug designation (https://www.drugcendr.com/news)

“The progress with the pancreatic cancer trial has exceeded our expectations” said Harri Jarvelainen, Chief Operating Officer of DrugCendR Inc. “Our near term goal is to validate the CEND-1 platform technology in multiple indications so clinicians can treat patients with cancers with high unmet medical need more effectively.”

Clinical update announced for DPX-Survivac program in Ovarian Cancer following positive feedback from FDA (https://ir.imv-inc.com/news-releases/news-release-details/imv-announces-clinical-update-dpx-survivac-program-ovarian)

> IMV Advances Phase 1b/2 Trial of DPX-Survivac Following Positive Feedback from FDA https://t.co/QT4qJFf1oq (https://t.co/QT4qJFf1oq) pic.twitter.com/15Q1Wz4pVg (https://t.co/15Q1Wz4pVg)
>
> — BioNews Services (@bionewsservices) February 9, 2019 (https://twitter.com/bionewsservices/status/1094121559332130817?ref_src=twsrc%5Etfw)

"This FDA meeting was an important milestone for the DPX-Survivac program, and we are very pleased to be aligned with the agency on key aspects of our clinical development plan," said Frederic Ors, Chief Executive Officer at IMV. "We believe that, with no currently approved immunotherapy options available, ovarian cancer remains a serious unmet medical need. We look forward to advancing our ongoing phase 2 DECIDE study in order to potentially expedite DPX-Survivac development as a possible first-in-class T cell immunotherapy treatment for patients with advanced ovarian cancer."

Lung-MAP precision medicine trial expands (https://www.swog.org/news-events/news/2019/01/29/lung-map-precision-medicine-trial-expands)

> Lung-MAP precision medicine trial expands to include more patients https://t.co/t835X3tQ98 (https://t.co/t835X3tQ98) pic.twitter.com/ZN8bkF7Vb7 (https://t.co/ZN8bkF7Vb7)
>
> — Bioengineer.org (@bioengineerorg) February 6, 2019 (https://twitter.com/bioengineerorg/status/1093230516361461760?ref_src=twsrc%5Etfw)

"We have more than 200,000 new cases of non-small cell lung cancer in the United States each year, and we desperately need new treatments," said Lung-MAP principal investigator Dr. Vali Papadimitrakopoulou, chief of thoracic medical oncology and professor of medicine at the University of Texas MD Anderson Cancer Center. "When most people are diagnosed with non-small cell lung cancer, their cancer has already grown and spread to other organs. If standard therapies don't work for these patients — and often they don't — they need alternatives. Lung-MAP provides those alternatives."

First cohort of patients dosed with COTI-2 +SOC in ongoing Ph 1b/IIa trial in solid tumors (http://globenewswire.com/news-release/2018/11/05/1645015/0/en/Cotinga-Pharmaceuticals-Announces-Research-Partnership-with-St-Vincent-s-University-Hospital-to-Evaluate-COTI-2.html)

"We are pleased with the progress we have made in dosing of cohort 1 patients in our COTI-2 plus cisplatin combination trial," said Alison Silva, President and Chief Executive Officer. "The patients in our ongoing Phase 1b/2a trial are suffering from a wide spectrum of cancers with little to no therapeutic options, and we are hopeful that combining existing chemotherapy regimens with COTI-2 could be a potential treatment. We remain committed to advancing the clinical development of COTI-2, and we will continue to provide key updates as the trial progresses."

LICENSING DEALS & COLLABORATIONS

Surface Oncology to retain worldwide rights for its first-in-class IL-27-targeting mAb SRF388 (https://investors.surfaceoncology.com/news-releases/news-release-details/surface-oncology-retains-worldwide-rights-its-first-class)

> Surface Oncology Retains Worldwide Rights for its First-in-Class Antibody Targeting IL-27, SRF388 https://t.co/8KkGqPdZa7 (https://t.co/8KkGqPdZa7) pic.twitter.com/d5xPYeaLBD (https://t.co/d5xPYeaLBD)
>
> — Stocks News Feed (@feed_stocks) February 4, 2019 (https://twitter.com/feed_stocks/status/1092538062473547776?ref_src=twsrc%5Etfw)

"SRF388 is an ideal program for Surface Oncology. We have conducted significant preclinical and translational work to understand IL-27's role in specific tumor types and have a focused translational strategy as we advance this program into clinical development," said Jeff Goater, chief executive officer of Surface Oncology. "We are pursuing an aggressive development timeline for SRF388, with an IND filing planned for the fourth quarter of this year."

Xencor and Genentech to develop and commercialize novel IL-15 immune activating cytokines including IL-15/IL-15Rα cytokine complex XmAb24306 (https://investors.xencor.com/news-releases/news-release-details/xencor-develop-and-commercialize-novel-il-15-immune-activating)

> Genentech Signs a Development and Commercialization Agreement with Xencor for its IL-15 & XmAb24306 Programs @genentech (https://twitter.com/genentech?ref_src=twsrc%5Etfw) https://t.co/Lz64D1jriX (https://t.co/Lz64D1jriX) pic.twitter.com/tYQf99hVKZ (https://t.co/tYQf99hVKZ)
>
> — PharmaShots (@Pharmashot) February 6, 2019 (https://twitter.com/Pharmashot/status/1093043888573558784?ref_src=twsrc%5Etfw)

"This partnership with Genentech accelerates our immuno-oncology work by enabling the exploration of novel XmAb24306 combinations with Genentech's leading oncology portfolio and our growing internal pipeline of bispecific antibodies," said Bassil Dahiyat, Ph.D., president and chief executive officer at Xencor. "A wide-ranging combination strategy will be critical to realize the potential of IL-15 bispecific cytokines such as XmAb24306, so we plan to explore our cytokines with a broad spectrum of leading commercial-stage and investigational cancer therapies."

Taiho Pharmaceutical and Cullinan Oncology to develop novel EGFR TKI TAS6417 (https://www.biospace.com/article/releases/taiho-pharmaceutical-and-cullinan-oncology-establish-collaboration-to-develop-tas6417-novel-egfr-tyrosine-kinase-inhibitor/)

> Taiho Pharmaceutical and Cullinan Oncology Establish Collaboration to Develop TAS6417 Novel EGFR Tyrosine Kinase Inhibitor: FIH Study in EGFR Exon 20 Insertions Will Commence in 2019 TOKYO and CAMBRIDGE Mass. Feb. 5 2019 PRNewswire Taiho Pharmaceutical... https://t.co/ZwizBOPbiU (https://t.co/ZwizBOPbiU)
>
> — CRO Contract Res. (@cro_bio) February 5, 2019 (https://twitter.com/cro_bio/status/1092817895996846087?ref_src=twsrc%5Etfw)

"The Taiho's drug research team created a unique molecule targeting EGFR Exon 20 insertion mutation using proprietary drug discovery platform technology. This alliance, one of the first of its kind at Taiho Pharmaceutical, allows our organization to optimize its R&D resource allocation and accelerate global development by accessing external talent and resources. We are pleased to partner with Cullinan Oncology and its experienced management team in bringing this novel treatment to NSCLC patients," said Teruhiro Utsugi, Managing Director of Taiho Pharmaceutical.

Merck and GSK to jointly develop and commercialize bifunctional fusion protein immunotherapy M7824 (bintrafusp alfa*) (https://www.merckgroup.com/en/news/m7824-2019-02-05.html?utm_source=press-release&utm_medium=email&utm_campaign=press-mailer&utm_content=en)

> . @GSK (https://twitter.com/GSK?ref_src=twsrc%5Etfw) to Co-Develop @merckgroup (https://twitter.com/merckgroup?ref_src=twsrc%5Etfw)'s #Cancer (https://twitter.com/hashtag/Cancer?src=hash&ref_src=twsrc%5Etfw) #Immunotherapy (https://twitter.com/hashtag/Immunotherapy?src=hash&ref_src=twsrc%5Etfw) Candidate M7824 in $4.2B Alliance: https://t.co/viWi1CHyNW (https://t.co/viWi1CHyNW) pic.twitter.com/AkhrcKMZqn (https://t.co/AkhrcKMZqn)
>
> — GEN (@GENbio) February 9, 2019 (https://twitter.com/GENbio/status/1094346469350490112?ref_src=twsrc%5Etfw)

"Our bifunctional fusion protein M7824 has the potential to bring new answers to patients living with cancer. Together with GSK we aim to drive a paradigm shift in the treatment of cancer as the leader in this novel class of immunotherapies," said Belén Garijo, Member of the Executive Board and CEO Healthcare of Merck. "GSK clearly emerged as the ideal partner due to their strong commitment to oncology, and the complementary talent and capabilities they will bring to our alliance. We now look forward to harnessing the full potential of M7824 across a broad range of cancer indications as we continue to advance our oncology portfolio."

argenx and Halozyme enter global collaboration and license agreement for ENHANZE® technology (https://www.argenx.com/en-GB/news-internal/argenx-and-halozyme-enter-global-collaboration-and-license-agreement-for-enhanze-technology/30212/)

> argenx ($ARGX) gains rights to Halozyme ($HALO)'s ENHANZE® drug delivery technology to develop #autoimmunedisease (https://twitter.com/hashtag/autoimmunedisease?src=hash&ref_src=twsrc%5Etfw) treatments for up to three targets: https://t.co/Q5JthZGR6A (https://t.co/Q5JthZGR6A)
>
> — GEN (@GENbio) February 4, 2019 (https://twitter.com/GENbio/status/1092542076984705024?ref_src=twsrc%5Etfw)

"Through our collaboration with Halozyme, a company that has transformed subcutaneous delivery of biologics, we now have the potential to add optimal delivery capabilities to our profile of building best-in-class antibodies against novel targets. By gaining exclusive access to ENHANZE® technology for our anti-FcRn asset, we also solidify our leadership position in this exciting new space that has the potential to disrupt the way severe autoimmune diseases are treated," commented Keith Woods, Chief Operating Officer of argenx. "As we look towards commercialization, if approved, efgartigimod is now equipped with a well-established subcutaneous delivery technology in addition to the clinical activity and favorable tolerability profile we have observed in studies to date. We believe that by offering both intravenous and subcutaneous formulations, we have the opportunity to capture patient preferences across all indications within our efgartigimod portfolio."

OTW Trivia

Deauville five-point scale (https://radiopaedia.org/articles/deauville-five-point-scale)

The Deauville five-point scale (Deauville 5ps) is an internationally-recommended scale for routine clinical reporting and clinical trials using FDG-PET/CT in the initial staging and assessment of treatment response in Hodgkin lymphoma (HL) (https://radiopaedia.org/articles/hodgkin-lymphoma?lang=us) and certain types of non-Hodgkin lymphomas (NHL) (https://radiopaedia.org/articles/non-hodgkin-lymphoma?lang=us) (DLBCL, MZL, CLL, SLL, LPL/WM, etc.)

On a scale ranging from 1 to 5, where 1 is best and 5 is the worst, FDG-avid (or previously FDG-avid) lesions are rated as on the basis of their uptake in mediastinum and liver as:

1. no uptake or no residual uptake (in interim analysis)
2. slight uptake, but less than blood pool (mediastinum)

3. uptake above mediastinal, but below or equal to uptake in the liver
4. slightly to moderately higher uptake than liver
5. distinctly high uptake or new lesion

Assessment of treatment response

- Complete response: Deauville scores of 1, 2 or 3 together without a bone marrow lesion
- Partial response: Score of 4 or 5, in addition to decreased uptake compared with baseline and no progression on CT
- Stable disease: Score of 4 or 5, in addition to decreased uptake compared with baseline
- Progressive disease: Score of 4 to 5 with higher uptake compared to baseline or any interim scan and/or any new lesions

Source: https://www.ncbi.nlm.nih.gov/pubmed/24712411 (https://www.ncbi.nlm.nih.gov/pubmed/24712411)

About the Author:

 (https://io.wp.com/www.sciwri.club/wp-content/uploads/2018/03/RT.jpg)

Richa (https://www.linkedin.com/in/richatewari/) earned her PhD at the National Brain Research Centre, India. For her thesis, she worked on the dreaded Glioblastoma multiforme. That was her first in-depth exposure to academic research in cancer biology. After her PhD, she expanded her research experience by working in the field of immunology at UCLA, USA. After her return to India, Richa switched to a corporate setting but continued her engagement with the cancer field. She is currently loving her work, which affords her the opportunity to continue developing her knowledge in the biomedical field of cancer. Outside of work, she enjoys watching, identifying and photographing birds.

Editor and Blog Design:

Abhi Dey (https://www.linkedin.com/in/abhinavdey/)

Abhi graduated from the Molecular Biophysics Unit of IISc (Bangalore, India) in 2011. As a Biomedical Scientist, he has worked with all three life-forms in his 13-year research career, viz., particulate, unicellular and multicellular. He is currently an Assistant Scientist at Emory University (Atlanta, GA) studying mechanisms of tumor recurrence in kids with brain tumors. As a postdoctoral fellow, he was the recipient of two Young Investigator Awards from Alex Lemonade Stand Foundation (Philadelphia, PA) and Rockland Immunochemicals. His current research has been funded by Northwestern Mutual Foundation (Milwaukee, WI), CURE Childhood Cancer Foundation (Atlanta, GA) and American Association for Cancer Research (AACR). When he is not on the bench you will find him spending time with his family or exploring the world through traveling and blogging.

Image Sources: Wikipedia and Twitter

Cover image: "Shown is a hematoxylin and eosin stained section through a plasmablastic lymphoma of the oral cavity in an HIV-positive adult male. There is a diffuse proliferation of large neoplastic cells most of which resemble B immunoblasts, plasmablasts or atypical plasma cells." Source (http://www.cellimagelibrary.org/images/43601)

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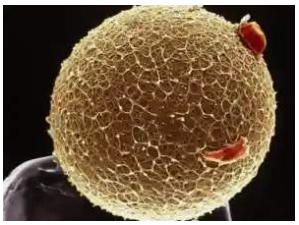

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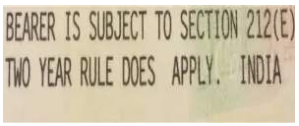

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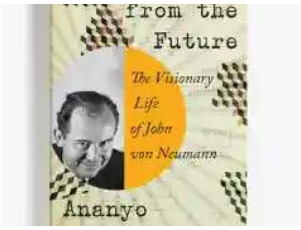

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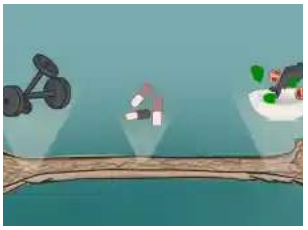

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